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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,857	09/15/2003	Yeon-su Lee	YPL-0064	4107
23413	7590	07/18/2006	EXAMINER	
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			BERTAGNA, ANGELA MARIE	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 07/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,857	Applicant(s) LEE ET AL.	
	Examiner Angela Bertagna	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/21/2004</u> <u>2/11/2004</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>4/11/2004</u> <u>12/19/2003</u> | |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-6, in the reply filed on June 26, 2006 is acknowledged. It is also noted that claims 7-12 were cancelled in the response filed June 26, 2006.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The disclosure is objected to because of the following informalities: Figures 1 and 2 contain nucleic acid sequences greater than 10 nucleotides in length that are not identified by the appropriate SEQ ID No: either in the Figure itself or in the "Brief Description of Drawings" section. See MPEP 2422.02.

Appropriate correction is required.

Art Unit: 1637

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Emens et al. (PNAS (1992) 89(16): 7300-7304).

Regarding claim 1, Emens teaches a nucleic acid fragment comprising a polymorphic site of SEQ ID No: 1 having adenine at position 1699 and comprising more than 10 contiguous nucleotides of SEQ ID No: 1 (see alignment below, where the corresponding fragment is underlined). This alignment was generated from GenBank Accession No. M95297, deposited by Emens et al. (see attached GenBank printout), and cited in the PNAS reference (page 7300).

```
RESULT 15
HAMHNF1A
LOCUS      HAMHNF1A                2452 bp    mRNA    linear    ROD 27-APR-
1993
DEFINITION Mesocricetus auratus (clone 2.5) hepatocyte nuclear factor 1-alpha
(HNF1a) mRNA sequence.
ACCESSION  M95297
VERSION    M95297.1  GI:191386
KEYWORDS   hepatocyte nuclear factor 1-alpha.
SOURCE     Mesocricetus auratus (golden hamster)
ORGANISM   Mesocricetus auratus
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Glires; Rodentia;
            Sciurognathi; Muroidea; Cricetidae; Cricetinae; Mesocricetus.
REFERENCE  1  (bases 1 to 2452)
AUTHORS    Emens, L.A., Landers, D.W. and Moss, L.G.
```

TITLE	Hepatocyte nuclear factor 1 alpha is expressed in a hamster insulinoma line and transactivates the rat insulin I gene
JOURNAL	Proc. Natl. Acad. Sci. U.S.A. 89 (16), 7300-7304 (1992)
PUBMED	1380153
COMMENT	Original source text: Mesocricetus auratus (library: HIT) pancreas cDNA to mRNA.

ORIGIN

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Query Match      81.6%;  Score 1547.2;  DB 6;  Length 2452;
Best Local Similarity  88.9%;  Pred. No. 0;
Matches 1685;  Conservative  0;  Mismatches  208;  Indels    3;  Gaps
1;

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Qy	1	ATGGT TTTCTAAACTGAGCCAGCTGCAGACGGAGCTCCTGGCGGCCCTGCTCGAGTCAGGG	60
Db	84	ATGGT TTTCTAAACTCAGCCAGCTGCAGACGGAGCTCCTGGCTGCCCTGCTCGAGTCCGGC	143
Qy	61	CTGAGCAAAGAGGCACTGATCCAGGCACTGGGTGAGCCGGGGCCCTACCTCCTGGCTGGA	120
Db	144	CTGAGTAAGGAGGCTTTGATTTCAGGCCTTGGGGGAGCCAGGGCCCTACCTGATGGTTGGA	203
Qy	121	GAAGGCCCCCTGGACAAGGGGGAGTCCTGCGGCGGCGGTGAGGGGAGCTGGCTGAGCTG	180
Db	204	GATGCTCCCTGGACAAGGGGGAGTCCTGCAGTGGGAGTCGAGGTGACCTGGCCGAGCTG	263
Qy	181	CCCAATGGGCTGGGGGAGACTCGGGGCTCCGAGGACGAGACGGACGACGATGGGGAAGAC	240
Db	264	CCCAATGGCCTGGGGGAGTCGCGTGTCTCGGAAGACGACACGGATGATGATGGGGAAGAC	323
Qy	241	TTCACGCCACCCATCTCTAAAGAGCTGGAGAACCTCAGCCCTGAGGAGGCGGCCCCACCAG	300
Db	324	TTCGCGCCACCCATTCTGAAAGAGTTGGAGAACCTCAGCCCGGAGGAGGCAGCCCCACCAG	383
Qy	301	AAAGCCGTGGTGGGAGACCCCTTCTGCAGGAGGACCCGTGGCGTGTGGCGAAGATGGTCAAG	360
Db	384	AAAGCCGTGGTGGGAGTCGCTTCTGCAGGACGACCCGTGGCGTGTGGCAAAGATGGTCAAG	443
Qy	361	TCCTACCTGCAGCAGCACAAATATCCCGCAGCGGGAGGTGGTCGATACCACTGGCCTCAAC	420
Db	444	TCCTATTTGCAGCAGCACAAATATCCCGCAGCGGGAGGTGGTCGACACCACGGGTCTCAAC	503
Qy	421	CAGTCCCACCTGTCCCAACACCTCAACAAGGGCACTCCCATGAAGACGCAGAAGCGGGCC	480
Db	504	CAGTCCCACCTGTGCGAGCACCTCAACAAGGGCACGCCCATGAAGACGCAGAAGCGGGCC	563

Qy	481	GCCCTGTACACCTGGTACGTCCGCAAGCAGCGAGAGGTGGCGCAGCAGTTACCCATGCA	540
Db	564	GCTCTGTACACCTGGTACGTCCGCAAGCAGCGAGAGGTGGCTCAGCAATTCACCCACGCG	623
Qy	541	GGGCAGGGAGGGCTGATTGAAGAGCCACAGGTGATGAGCTACCAACCAAGAAGGGGCGG	600
Db	624	GGGCAAGGGGGACTGATCGAAGAGCCACCGGTGACGAGCTGCCGACCAAAAAGGGAAGG	683
Qy	601	AGGAACCGTTTCAAGTGGGGCCAGCATCCCAGCAGATCCTGTTCCAGGCCTATGAGAGG	660
Db	684	AGGAACCGGTTCAAGTGGGGCCCGCATCCCAGCAGATCCTGTTCCAGGCCTATGAGAGG	743
Qy	661	CAGAAGAACCCTAGCAAGGAGGAGCGAGAGACGCTAGTGGAGGAGTGCAATAGGGCGGAA	720
Db	744	CAGAAGAATCCCAGCAAGGAAGAGCGGGAGACCTTGGTGGAGGAGTGTAACAGGGCGGAG	803
Qy	721	TGCATCCAGAGAGGGGTGTCCCATCACAGGCACAGGGGCTGGGCTCCAACCTCGTCACG	780
Db	804	TGCATCCAGAGGGGGGTGTCAACATCACAGGCACAGGGGCTAGGCTCCAACCTTGTACG	863
Qy	781	GAGGTGCGTGTCTACAACCTGGTTTGCCAACCGGCGCAAAGAAGAAGCCTTCCGGGCACAAG	840
Db	864	GAGGTGCGTGTCTACAACCTGGTTTGCCAACCGGCGCAAGGAAGAAGCCTTTCGGGCACAAG	923
Qy	841	CTGGCCATGGACACGTACAGCGGGCCCCCCCCAGGGCCAGGCCCGGGACCTGCGCTGCCC	900
Db	924	CTGGCCATGGACACATACAACGGACCCCCACCCAGGCCAGGCCAGGGCCACACTGTCT	983
Qy	901	GCTCACAGCTCCCCCTGGCCTGCCTCCACCTGCCCTCTCCCCCAGTAAGGTCCACGGTGTG	960
Db	984	GCTCACAGCTCCCCCTGGCCTGCCCACATCCGCCCTCTCCCCCAGTAAGGTCCACGGTGTG	
Qy	961	CGCTATGGACAGCCTGCGACCAGTGAGACTGCAGAAGTACCCTCAAGCAGCGGCGGTCCC	
Db	1044	CGGTACGGACAGCCTGCAACCAGTGAGGCAGCTGAGGTGCCCTCAAGCAGCGGTGGTCCC	
Qy	1021	TTAGTGACAGTGTCTACACCCCTCCACCAAGTGTCCCCACGGGCCTGGAGCCCAGCCAC	
Db	1104	TTAGTGACAGTGTCTGCGGCTTTACACCAAGTGTGCGCCACAGGCCTGGAGCCCAGCAGC	
Qy	1081	AGCCTGCTGAGTACAGAAGCCAAGCTGGTCTCAGCAGCTGGGGGCCCCCTCCCCCTGTC	
Db	1164	AGCCTGCTGAGCACTGAAGCCAAGTTGGTCTCAGCCACTGGGGGTCCCCTGCCTCCAGTC	
Qy	1141	AGCACCCCTGACAGCACTGCACAGCTTGGAGCAGACATCCCCAGGCCTCAACCAGCAGCCC	
Db	1224	AGCACCCCTGACAGCACTGCACAACTTGGAGCAGACGTCTCCAGGTCTCAACCAGCAGCCA	
Qy	1201	CAGAACCTCATCATGGCCTCACTTCTGGGGTCATGACCATCGGGCCTGGTGAGCCTGCC	
Db	1284	CAGAACCTCATCATGGCTTCACTGCCTGGGGTCATGACCATTGGACCTGGGGAGCCTGCC	
Qy	1261	TCCCTGGGTCTTACCTTACCAACACAGGTGCCTCCACCCTGGTCATCGGCCTGGCCTCC	

Art Unit: 1637

Db	1344	TCCCTGGGCCCCACATTCACTAACACAGGCGCCTCTACCCTGGTCATTGGTCTGGCCTCC
Qy	1321	ACGCAGGCACAGAGTGTGCCGGTCATCAACAGCATGGGCAGCAGCCTGACCACCCTGCAG
Db	1404	ACTCAGGCACAGAGTGTGCCGGTCATCAACAGCATGGGCAGCAGCCTGACCACCCTGCAG
Qy	1381	CCCGTCCAGTTCTCCCAGCCGCTGCACCCCTCCTACCAGCAGCCGCTCATGCCACCTGTG
Db	1464	CCGGTCCAGTTCTCCCAGCCACTGCACCCCTCCTACCAGCAGCCACTCATGCCCCCTGTA
Qy	1441	CAGAGCCATGTGACCCAGAACCCCTTCATGGCCACCATGGCTCAGCTGCAGAGCCCCAC
Db	1524	CAGAGCCACGTGGCCCAGAGTCCCTTCATGGCCACCATGGCCAGCTGCAGAGCCCCAC
Qy	1501	GCCCTCTACAGCCACAAGCCCGAGGTGGCCAGTACACCCACACGGGCCTGCTCCCGCAG
Db	1584	GCCCTCTACAGCCACAAGCCTGAGGTGGCCAGTACACGCACACAAGCCTGCTTCCGCAG
Qy	1561	ACTATGCTCATCACCGACACCACCAACCTGAGCGCCCTGGCCAGCCTCACGCCCACCAAG
Db	1644	ACTATGCTGATCACGGAC--ACCAACCTCAGCGCCCTTGCCAGCCTCACGCCCACCAAG
Qy	1621	CAGGTCTTCACCTCAGACACTGAGGCCTCCAGTGAGTCCGGGCTTCACACGCCGGCATCT
Db	1701	CAGGTCTTCACCTCAGACACAGAGGCCTCCAGTGAGCCTGGACTTCATGAACCATCGTCT
Qy	1681	CAGGCCACCACCCTCCACATCCCCAGCCAGGACCCTGCCGGCATCCAGCACCTGCAGCCG
Db	1761	CCAGGCCACCACCATCCACATCCCCAGCCAGGACCCTAGCATCCAGCACCTGCAGCCG
Qy	1741	GCCCACCGGCTCAGCGCCAGCCCCACAGTGTCTCCAGCAGCCTGGTGCTGTACCAGAGC
Db	1821	GCTCACCAGGCTCAGCACAGTCCCACCGTGTCTCCAGCAGCCTGGTGTGTACCAGAGC
Qy	1801	TCAGACTCCAGCAATGGCCAGAGCCACCTGCTGCCATCCAACCACAGCGTCATCGAGACC
Db	1881	TCGGACTCCACCAACGGGCATAGCCACCTGCTGCCATCCAACCATGGTGTCTATCGAGACT
Qy	1861	TTCATCTCCACCCAGATGGCCTCTTCCTCCAGTAA 1896
Db	1941	TTTATCTCCACCCAGATGGCCTCCTCCTCCAGTAA 1976

Regarding claim 2, the fragment of Emens comprises 22 contiguous nucleotides (see above alignment).

Regarding claims 3 and 4, Emens teaches an allele-specific oligonucleotide hybridizing to the fragment of claim 1, or a complement thereof (see Methods section, page 7000, col. 2,

Art Unit: 1637

where the above sequence, including the underlined fragment, was used as a specific probe for a complementary sequence).

6. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (US 2004/0181048 A1; filed August 8, 2001).

Regarding claim 1, Wang teaches a nucleic acid fragment comprising more than 10 contiguous nucleotides of SEQ ID No: 3 and the polymorphic nucleotide T at position 29 (see alignment below). This alignment was generated from SEQ ID No: 519026 of Wang.

RESULT 4

```
; Publication No. US20040181048A1
; GENERAL INFORMATION:
; APPLICANT: Wang, David G.
; TITLE OF INVENTION: Identification and Mapping of Single
; TITLE OF INVENTION: Nucleotide Polymorphisms in the Human Genome
;
; SEQ ID NO 519026
; LENGTH: 678
; TYPE: DNA
; ORGANISM: Homo sapiens
```

```
Query Match          100.0%; Score 93; DB 4; Length 678;
Best Local Similarity 100.0%; Pred. No. 2e-18;
Matches 93; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

Qy      1  GTAAGGTCCAGGCCTGCTGGCCCTCCCTTGGCCTGTGACAGAGCCCCTCACCCCCACATC  60
      ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      359 GTAAGGTCCAGGCCTGCTGGCCCTCCCTTGGCCTGTGACAGAGCCCCTCACCCCCACATC  300

Qy      61  CCCC GGGCTCAGGAGGCTGCTCTGCTCCCCCAG  93
      ||||||||||||||||||||||||||||||||
Db      299 CCCC GGGCTCAGGAGGCTGCTCTGCTCCCCCAG  267
```

Regarding claim 2, the fragment of Wang is 93 nucleotides in length (see above).

Regarding claims 3 and 4, Wang teaches an allele-specific oligonucleotide probe hybridizing to a complement of the nucleic acid fragment of claim 1 (the above fragment

Art Unit: 1637

hybridizes specifically to an oligonucleotide fragment complementary thereto; see also paragraphs 10 and 20-21, where Wang teaches that the fragments may be used as probes).

Regarding claims 5 and 6, Wang teaches that the above fragment may function as a primer with the 3' end arranged at the polymorphic site of the fragment (see paragraph 21).

Conclusion

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EBI database accession number AC079602.15 (cited in IDS filed April 1, 2004) also teaches a nucleic acid fragment of claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna
Patent Examiner
Art Unit 1637

amb


JEFFREY FREDMAN
PRIMARY EXAMINER

7/14/06